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HOWARD EISENBERG, ESQ. 1220 LIMBERLOST LANE GLADWYNE, PA 19035			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 07/21/08 in response to the non-final Office Action mailed 04/23/08.

### **Status of Claims**

- 2) Claim 48 has been amended via the amendment filed 07/21/08.  
New claims 49-51 have been added via the amendment filed 07/21/08.  
Claims 1, 2, 15-17, 36-39 and 46-51 are pending.  
Claims 1, 2 and 48-51 are under examination.

### **Prior Citation of References**

- 3) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Withdrawn**

- 4) The rejection of claim 48 made in paragraph 6 of the Office Action mailed 04/23/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 48.
- 5) The rejection of claim 48 made in paragraph 8 of the Office Action mailed 04/23/08 under 35 U.S.C § 103(a) as being unpatentable over Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001, already of record) or Fang *et al.* (*FEMS Microbiol. Lett.* 176: 91-96, 1999 – Applicants' IDS) in view of Hammerschmidt *et al.* (*Infect. Immun.* 67: 1683-1687, April, 1999) or Staggs *et al.* (*Mol. Microbiol.* 12: 613-619, 1994) or Biswas *et al.* (*Infect. Immun.* 67: 455-459, January 1999), is withdrawn in light of Applicants' amendment to the claim.
- 6) The rejection of claims 1 and 2 made in paragraph 8 of the Office Action mailed 04/23/08 under 35 U.S.C § 103(a) as being unpatentable over Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248,

February 2001, already of record) or Fang *et al.* (*FEMS Microbiol. Lett.* 176: 91-96, 1999 – Applicants' IDS) in view of Hammerschmidt *et al.* (*Infect. Immun.* 67: 1683-1687, April, 1999) or Staggs *et al.* (*Mol. Microbiol.* 12: 613-619, 1994) or Biswas *et al.* (*Infect. Immun.* 67: 455-459, January 1999), is withdrawn upon further consideration and in light of Applicants' arguments. Applicants cite Jiang (WO 98/21231) which shows that the ATCC 13387 strain of *S. uberis* produces a lactoferrin-binding protein (LBP). The structure of the LBP shown in Figure 2A of Jiang differs from the structure of the instantly claimed polypeptide.

**Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

7) Claims 49-51 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 49 includes the limitations: 'the purified polypeptide of claim 1 which comprises extending from the carboxy terminal amino acid of SEQ ID NO: 4, an additional amino acid sequence consisting of a portion or all of amino acids 81 to 905 of SEQ ID NO: 15'. New claim 50 includes the limitations: 'wherein the additional amino acid sequence is all of amino acid 81 to amino acid 905 of Seq. ID NO: 15'. New claim 51 includes the limitations: 'the purified polypeptide of claim 49 wherein the additional amino acid sequence is from amino acid 81 to an amino acid before amino acid 905 of SEQ ID NO: 15'. Applicants state that support for the new claims is found on pages 7-10 of the specification which disclose that pepSUAM (SEQ ID NO: 4) is the amino terminal portion of SUAM (SEQ ID NO: 15), and that the amino acid sequence of SEQ ID NO: 4 is that of amino acids 66-80 of SEQ ID NO: 15. However, these parts of the specification do not provide support for the new claims. Claim 49 encompasses within its scope polypeptides with 66-100, 66-91, 66-301, 66-542, 66-905 etc. amino acids from SEQ ID NO: 15. However, purified polypeptide fragments of such precise size are not supported by the instant specification, as originally filed. The top of page 9 of the specification describes six amino acid long polypeptides of pepSUAM (SEQ ID NO: 4), but not of SUAM. Likewise, the full paragraph on page 9 of the specification describes 6 to 15 amino acid-long polypeptides of SEQ ID NO: 4. One sentence therein states the following [Emphasis

added]:

The polypeptide of the invention may further contain additional amino acids to the amino terminal or *carboxy* terminal sides of the sequence that is *a portion or all of pepSUAM*.

These parts fail to support the above-identified limitations in the new claims. Therefore, the above-identified limitations in the claim(s) and the now claimed scope of the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**8)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**9)** Claims 2 and 49-51 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 2 is indefinite and is improperly broadening in scope in the limitation: 'polypeptide ... has an amino acid sequence that consists essentially of the amino acid sequence of SEQ ID NO: 4'. Claim 2 depends from claim 1. The polypeptide of claim 1 already has an amino acid sequence comprising the amino acid sequence of SEQ ID NO: 4. Is 'an amino acid sequence' recited in line 2 of claim 2 other than the amino acid sequence recited in claim 1? It is unclear how the dependent claim 2 further limits claim 1.

(b) Claim 49 is vague and indefinite in the limitation: 'a portion ... of amino acids 81 to 905 of SEQ ID NO: 5', because it is unclear what is encompassed in the limitation 'portion'. How much of amino acids 81 to 905 of SEQ ID NO: 5 have to be present in order to qualify as a 'portion' is not clear.

(c) Claim 50 is indefinite, incorrect, and inconsistent with the language used in claim 49 in the limitation: 'amino acid 81 to amino acid 905 of Seq. ID NO: 15'. It is suggested that Applicants replace the above-identified limitation with the limitation --amino acids 81 to 905 of SEQ ID NO: 15--.

(d) Claim 51, which depends from claim 49, is also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### Remarks

**10)** Claims 2 and 49-51 stand rejected. Claims 1 and 48 are allowable.

**11)** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**12)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**13)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**14)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/  
S. Devi, Ph.D.  
Primary Examiner  
AU 1645

October, 2008